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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,432	08/07/2003	Luc Uylenbroeck	2003_1110	8533
513	7590	08/30/2005	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			SPIVACK, PHYLLIS G	
2033 K STREET N. W.				
SUITE 800			ART UNIT	
WASHINGTON, DC 20006-1021			PAPER NUMBER	
			I614	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,432

Applicant(s)

UYLENBROECK ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-20 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-20, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

5.00

An Amendment filed June 15, 2005 is acknowledged. Claims 21 and 22 are/were canceled. Claims 12-20 and 23 remain under consideration.

Claims 12, 13 and 15-20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Subsequent to the recent amendment to independent claims 12 and 13, in which the limitation "wherein the infant or child has never been affected by asthma" has been added, an issue of redundancy remains. The claims recite "preventing the onset of asthma" which essentially requires what the new limitation recites, i.e., "wherein the infant or child has never been affected by asthma". Preventing a condition means stopping it in advance. In this case, preventing the onset of asthma means never having been affected by asthma.

Claims 12-20, 22 and 23 were rejected in the last Office Action under 35 U.S.C. 103(a) as being unpatentable over Trieloff, I., TW Padiatrie. It was asserted Trieloff teaches preventive therapy with cetirizine for children aged 1-2 years wherein the onset of asthma has not occurred and wherein a parent or sibling has atopic dermatitis.

Applicants argue the infant or child in the ETAC study may already have a history of asthma and that nothing in the Trieloff document suggests to the skilled person that it would be essential to guarantee the success of the claimed methods that children have never been affected by asthma. Further, Applicants urge no one can predict the result of the study with any reasonable degree of certainty and cite five passages in the document as support.

Although the infant or child in the ETAC study may already have a history of asthma, the language encompasses those subjects who do not have a history of asthma. Further, there is no guarantee of success in practicing the present methods because prevention is absolute. Questions of mere speculation, that Applicants have raised relating to the prior art, apply as well to the present methods. Having atopic dermatitis or having a parent or a sibling suffering from neurodermatitis, asthma or allergic rhinitis does not absolutely predict the onset of asthma in an infant or child. One skilled in the art, in view of Trelloff's teaching, would have been motivated to administer cetirizine to inhibit the onset of asthma in high-risk small children.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record under 35 U.S.C. 103 is maintained over claims 12-20 and 23 for the reasons of record. Trelloff suggests a preventative therapy with a reasonable expectation of success.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

August 24, 2005